



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,669	12/19/2001	Kimiyuki Shibuya	49301-DIV (71526)	1645

21874 7590 11/07/2003

EDWARDS & ANGELL, LLP

P.O. BOX 9169

BOSTON, MA 02209

EXAMINER

DENTZ, BERNARD I

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 11/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/034,669

Applicant(s)

SHIBUYA ET AL.

Examiner

Bernard Dentz

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/381,850.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) and 3 references.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1625

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

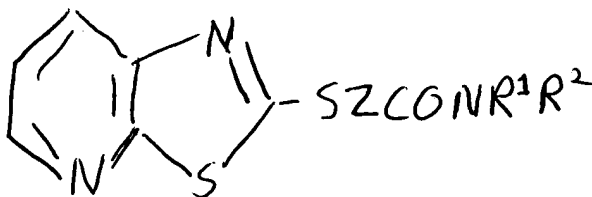
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 14-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Otsuka, Japanese Kokai Tokkyo Koho 58-116489.

It discloses as anti-inflammatories, antihypertensives, ~~analgesics~~ analgesics and antipyretics compounds of the formula:

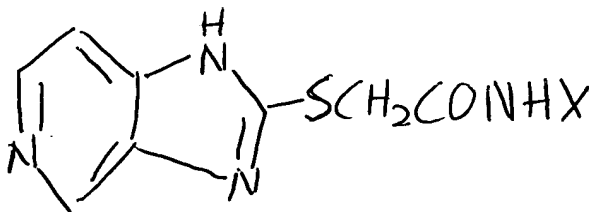


where Z is optionally substituted alkylene and R¹ and R² are H, alkyl, cycloalkyl, alkenyl or optionally substituted phenyl. See the chemical abstract and page 1200 of the patent. See compounds 6-9. In 6 and 7 Z is ethylene and in 8 and 9 it is 1, 3-propylene.

The disclosed hypertensive use anticipates applicants' use claims since applicants state that their compounds are used to treat cerebrovascular diseases. It is known that anti-hypertensives can be useful in treating cerebrovascular disease.

Claims 14-19, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Czarnocka-Janowicz et al.

This article discloses the synthesis and tuberculostatic activity ^{of} amides of the formula:



Where X can be phenyl, and ortho, meta or para-tolyl. See the chemical abstract, the scheme at p. 530, especially compounds VID, VIh, VIi and VIj. See also the Table, at p. 532 and p. 533 where VIi the compound wherein X is phenyl is shown to have pretty good tuberculostatic activity.

The synthetic method is disclosed under 5, at the bottom of p. 532.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1625

Claims 14-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Otsuka, supra.

The halo, alkyl, etc. homologs of the small genus disclosed by and the specific compounds made by the reference would have been ^{obvious} to the ordinarily skilled worker.

Claims 14-19, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Czarnocka-Janowicz et al, supra.

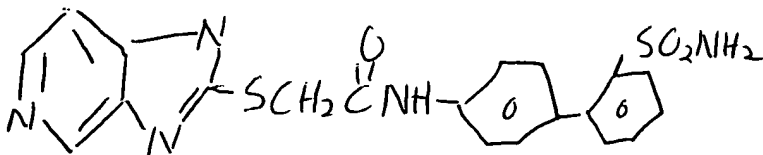
Again the halo, alkyl, etc. homologs of the small genus of (N-aryl)-2-imidazo[4, 5-C] pyridin-2-ylthio-acetamides disclosed by and the specific members thereof made by the reference would have been obvious to the ordinarily skilled worker.

Claims 14 and 17-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Dominguez et al, US Patent 5,886,191.

It discloses compounds which are inhibitors of thrombin and Factor Xa. See top of col. 1 and col. 78 under Utility. At the latter place the compounds are disclosed as useful in treatment of ischemic attack, atherosclerosis, myocardial infarction cerebrovascular thromboembolic disorders ^{and} cardiovascular disorders which are the same or similar to some of the instant claimed utilities.

The compounds which are encompassed by the instant genus are

Art Unit: 1625



and its N-t-butyl derivative, the synthesis of which is taught in Ex. 67 and 66 respectively. See also Table 21 at col. 77 and 78 where several other close analogs are taught.

Claims 14, 16-19, 22 and 25 are rejected under 35 USC 112 for failing to particularly point out the invention. "General" in claims 14 and 16 opens the claimed genus to unsupported compounds. "Use of claims" 22 and 23 are improper because the step involved in using is not recited. In claim 25, line 1 after "agent" -f- is inapt.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bernard Dentz whose telephone number is (703) 308-4544. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703) 308-4698. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Dentz/LR
November 4, 2003

BERNARD DENTZ
PRIMARY EXAMINER
GROUP 1630